

PSJ15 Exh 70

From: Ratliff, Bill
Sent: Friday, August 14, 2009 2:31 PM
To: Harper, Karen
Subject: RE: Suspicious Order Monitoring Report: Southern California Compounding Pharmacy Order Inquiry

Shouldn't you say we are canceling them because we do not believe their registration supports the addition?

Bill Ratliff
Director of Security
Covidien
314-654-8112
24 hours 314-654-1600
bill.ratliff@covidien.com

From: Harper, Karen
Sent: Friday, August 14, 2009 9:00 AM
To: Kleissle, Paul (Pete) D.
Cc: Ratliff, Bill
Subject: Suspicious Order Monitoring Report: Southern California Compounding Pharmacy Order Inquiry

Pete,
FYI

We previously corresponded with DEA (March, 2009) about this customer and they decreased their Fentanyl order from 50 grams to 25 grams.
Customer now requests more frequent deliveries and wants to order Hydromorphone.

Karen Harper
Controlled Substance Compliance
Global Logistics Manager
Covidien/Mallinckrodt
Telephone (office) (314) 654-1868
Telephone (cellular) (314) 401-1573
karen.harper@covidien.com

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From: Harper, Karen
Sent: August 12, 2009 7:28 AM
To: Pokorny, Camille M
Cc: Ratliff, Bill; Stewart, Cathy; Hunter, Dave
Subject: Southern California Compounding Pharmacy Order Inquiry

Camille,
Per our conversations, customer has inquired about increasing the frequency of their Fentanyl orders or increasing the quantity of their Fentanyl orders.
Further, they intend to purchase Hydromorphone powder as well.

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Customer operates using a Retail Pharmacy DEA Registration.

Mallinckrodt interpretation of the regulations is as follows:

Retail Pharmacy

Compounds medications to fit the unique needs of the patient, as authorized by a prescription from physician.

The medications must be dispensed directly to a patient and not sent to the physician.

DEA **does not require** quota issuance for acquisitions by Retail Pharmacy registrants, distributions of CI and CII require DEA 222 order forms.

Note: The Mallinckrodt business model does not include direct sales to Retail Pharmacy registrants.

Compounding Pharmacy

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DEA requires Compounding Pharmacy registrants to be licensed within the category of Manufacturing registrants.

Manufacturing registrants **require quota** for acquisitions of CI and CII controlled substances, distributions of CI and CII require DEA 222 order forms.

Note: The Mallinckrodt business model accommodates sales to Compounding Pharmacy/Manufacturing registrants, upon proof of current DEA registration license, provided they certify in writing that the firm has available Procurement Quota issued by DEA, adequate to cover the quantity of the specific sale.

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From: Ratliff, Bill
Sent: Friday, August 14, 2009 2:34 PM
To: Harper, Karen
Subject: FW: Southern California Compounding Pharmacy Order Inquiry

What do you think?

Bill Ratliff
 Director of Security
 Covidien
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 24 hours 314-654-1600
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From: Stewart, Cathy
Sent: Friday, August 14, 2009 11:39 AM
To: Harper, Karen; Pokorny, Camille M
Cc: Ratliff, Bill; Hunter, Dave; Montano, Allyne
Subject: RE: Southern California Compounding Pharmacy Order Inquiry

Based on our conversations we're going to ask OJ to obtain from the DEA, in writing, that its' okay for them to purchase 50 gram quantities, x number of times per month for distribution to physicians under the Retail Pharmacy license. Upon receipt and review of that communication we'll review.

I guess the next question would be whether or not the Specialty Pharmaceuticals business would have heart burn that API is selling to their customers (taking business away from Medisca, etc).

Cathy

From: Harper, Karen
Sent: Wednesday, August 12, 2009 7:28 AM
To: Pokorny, Camille M
Cc: Ratliff, Bill; Stewart, Cathy; Hunter, Dave
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